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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,820	07/05/2001	Nancy A. Noble	304344USWO	8977

26941 7590 06/04/2003

MANDEL & ADRIANO
55 SOUTH LAKE AVENUE
SUITE 710
PASADENA, CA 91101

EXAMINER	
MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,820	NOBLE ET AL.	
	Examiner	Art Unit	
	Sean R McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *5,7,8,14,24,27-29 and 50-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9-13,15-17,19-23,25,26,30-34 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, Claims 1-31 and 55 in Paper No. 10, filed 3/26/03 is acknowledged. The traversal is on the ground(s) that the art indicated as showing destruction of novelty and thus any special technical feature. Applicant argues that the claims require a combination of agents, one agent to degrade excess ECM and one to inhibit TGFβ (claims 9-14 and 55) or a by using a combination of agents to inhibit TGFβ. This is not found persuasive because of the art rejection set forth below as evidence of lack of novelty and hence a lack of a special technical feature. Further it is noted that the claims do not require that the agents function only as an inhibitor of ECM or only as an inhibitor of TGFβ. The art clearly shows that TGFβ inhibitors also function to degrade ECM via their inhibition of TGFβ inhibition of proteases, for example. Claims 32-34, however, will be rejoined in the examination of the instant application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 35-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 5, 7, 8, 14, 18, 24, and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 4, 6, 9-13, 15-17, 21-23, 25, 26, and 31-34 rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al [Applicant citation 110 on form 1449, filed 11/23/01] and evidenced by Moll et al [Kidney International, Vol. 48:1459-1468, 1995].

Peters et al disclose the administration of an ACE inhibitor (ENALEPRIL^{tm}) and an Ang II receptor blocker (LOSARTIN^{tm}) to animal models of renal disease (associated with TGFβ over expression). Peter et al have disclosed the following: both of the above compounds inhibit TGFβ activity; overproduction of TGFβ leads to matrix accumulation and tissue fibrosis; TGFβ over expression causes increased synthesis of matrix proteins, causes decreased degradation of matrix proteins by suppression of protease expression and increased expression of protease inhibitors such as TIMP (a metalloproteinase inhibitor). Moll et al have disclosed that TGFβ decreases synthesis of proteases such as tPA. The classification of the two agents above as both inhibitors of TGFβ activity and Agent for decreasing extracellular matrix are clearly within the context of the claimed invention since, for example, claim 11 requires only the administration of

an agent that increases the amount of active protease sufficient to degrade excess accumulated matrix. The administration of a TGFβ inhibitor will decrease TGFβ activity, which will increase the expression of tPA, which will increase the production of proteases to degrade ECM, for example. It is noted (for claim 20) that a protease expressed in a cell would be encoded by a nucleic acid.

Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters as applied above, and further in view of Border et al [WO 96/25178].

The claimed invention is drawn to the inhibition of TGFβ and degradation og ECM via the administration of TGFβ inhibitors and/or an agent for degrading ECM.

Peters is relied upon as above to show that TGFβ inhibitors act as ECM degradation agents and also to show that there is motivation to combine TGFβ inhibitors in a treatment (see page 1578, right column, for example).

Border et al have taught the use of nucleic acids to express desired TGFβ inhibitors in a treatment, for example. The entire document addresses this type of administration of TGFβ inhibitors. Border et al do not specifically teach a combination of inhibitors in a treatment, however it is noted that Border et al have provided such a motivation to combine and further MPEP 2144.06 indicates that it is *prima facie* obvious to combine equivalents known for the same purpose, therefore one in the art would clearly have known to combine the administration of nucleic acids encoding TGFβ inhibitors such as antibodies, decorin, etc.

The invention as whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
June 2, 2003

SEAN McGARRY
PRIMARY EXAMINER
1635